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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,339	08/28/2000	David A. Epstein	0942.4630001/RWE/BJD	8261

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

14

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/650,339

Applicant(s)
Epstein et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 20, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-37, and 44-61 is/are pending in the application.
- 4a) Of the above, claim(s) 5-7, 13, 28-30, 36, 48-53, and 56-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-12, 14-18, 20-27, 31-35, 37, 44-47, 54, 55, 60, and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 1-18, 20-37, 44-61 are pending. Claims[?] are considered on the merits. Claims 5-7, 13, 28-30, 36, 48-53, 56-59 are withdrawn from consideration as being drawn to a non-elected invention. Claims 19, 38-43 have been canceled.

Newly submitted claims 56-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The election of species by applicant was hydroxypyridine derivative, see paper # 9.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 1-4, 8-12, 14-18, 20-27, 31-35, 37 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In claims 1 and 24, the insertion of the limitation "with the proviso that said transition metal binding compound is not citrate", has no support in the as-filed specification. Claim 61 has a like intended recitation. The insertion of this limitation is a new concept because it does not have support in the narrative portion of the as-filed specification by way of generic disclosure, which would show possession of the concept of the exclusion of citrate with the inclusion of all other transition metal compounds. This is a matter of written description. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Ex parte Grasselli *et al.* 231 USPQ 393 is considered by the examiner to be analogous to the present case because the common issue is whether the composition of the claims which is open to further inclusion of other elements

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or components not expressly excluded in the amendment is a new concept. In the instant case, as in *Ex parte Grasselli*, no support is found for this concept in the examples, originally filed claims or disclosure as-filed.

The instant examples do not support the exclusion of the complexing compound, citrate and the inclusion of all other complexing components. The originally filed claims are open to further substitution without limit (comprising). The generic disclosure of the instant specification under "Brief Summary of Invention" also has open language (comprise) on page 7, line 19. Thus, the originally filed claims and disclosure support the inclusion of all transition metal binding compounds in the composition including citrate. Thus, applicants' specification demonstrates no intent to exclude citrate from the composition at the time of filing.

The exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

While applicants may argue that none of the examples show the inclusion of citrate, ~~However~~, the claims are not limited to the exemplified metal binding compounds in the exemplified compositions. The concept which has been introduced is the exclusion of a specific component (citrate) in the composition of the claims while the composition remains open to all further inclusions of transition metal binding components. This is the new concept. Please see *Ex parte Grasselli et al.* for further explanation.

INDEFINITE

Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 repeats an ingredient twice, namely (iii) and (v). Thus, the intended composition is unclear.

Claim Rejections - 35 USC § 102

Claims 44-47, 54, 60, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Murad *et al.*

(54)

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The claims are directed to a kit which comprises (either a medium OR a medium ingredient OR a transition element OR a transition element complex OR a cell) AND (either a transition metal binding compound OR a transition element complex).

Murad *et al.* exemplifies the composition of 2-hydroxypyridine-N-oxide in DMEM with calf serum (Table I) and cells.

Applicants argue that Murad *et al.* does not disclose a kit. As the claimed kit may consist only of a medium which contains a transition metal ion and a complexing compound, and does not have any structural elements, whether one calls the medium a kit or not is considered to be an exercise in semantics and as such, is not a limitation which is given much patentable weight.

Claims 44-47, 54, 60, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Testa *et al.*

Testa *et al.* disclose the composition of picolinic acid, a hydroxypyridine derivative, in RMPI with BSA and cells, see Material and Methods and Figure 1.

Applicants argue that Testa *et al.* does not disclose a kit. As the claimed kit may consist only of a medium which contains a transition metal ion and a complexing compound, and does not have any structural elements, whether one calls the medium a kit or not is considered to be an exercise in semantics and as such, is not a limitation which is given much patentable weight.

Claims 1-4, 8, 11, 12, 15-18, 20-27, 31, 34, 35, 44-47, 54, 55, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Waymouth.

The claims are directed to a serum free culture medium comprising a transition metal and a complexing compound and a kit which may comprise a medium containing a transition metal and a complexing compound.

Applicant argues that the examiner has not established that amino acids are transition metal binding compounds. Please read claim 4, where amino acids are claimed as transition metal binding compounds. The examiner is not required to prove that the claimed elements are enabled by the disclosure.

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In any case, please read Table 1, where a hydroxypyridine derivative, pyridoxin, is a component of the medium.

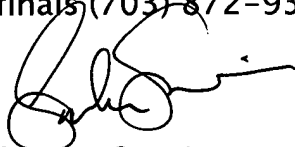
Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after hours (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
February 25, 2002